## **REMARKS**

Claims 1-9, 12, 13, 18, and 22 are pending. Claims 1-9, 12, and 13 have been rejected. Claims 18 and 22 have been objected to.

## Claim Rejection - 35 U.S.C. § 112

The Examiner has rejected under 35 U.S.C. § 112, first paragraph, Claim 13 as failing to comply with the written description requirement. Specifically, the Examiner contends that the subject matter of Claim 13 is new matter, as the specification discloses condylar components joined by a pin *or* permanently joined together.

Applicant respectfully submits that the specification provides support for the subject matter of Claim 13. Specifically, referring to paragraph 22 of the present application, the specification states:

"The condylar components 20 and intercondylar component 22 may be joined together to form the tibial bearing insert 12 in a variety of ways. The components may be provided as a modular kit of parts that are joined together intraoperatively by the surgical staff to permit customizing the implant to a particular patients needs. Alternatively, the components may be permanently joined together at the time of manufacturing and supplied as a one piece tibial bearing insert 12."

[0022]

The specification of the present application then continues and provides a variety of ways in which the components may be joined together either interoperatively or at the time of manufacture. See ¶[0022]. One of the ways disclosed for joining the components is by mechanical fasteners, such as pins 28, shown in Figures 2 and 3.

For the foregoing reasons, Applicant respectfully submits that the subject matter of Claim 13 is fully supported by the specification of the present invention and respectfully requests withdrawal of the 35 U.S.C. § 112, first paragraph, rejection thereof.

## Claim Rejections - 35 U.S.C. § 103(a)

Claims 1-6, 9, and 12 are rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,709,461 to O'Neil et al. ("O'Neil '461") in view of U.S. Patent No. 6,365,089 to Krebs et al. ("Krebs '089").

O'Neil '461 discloses tibial component 10, shown in Figures 1-3A, including tibial bearing insert 12, tibial plateau 14, and securing member 16. Tibial bearing insert 12 includes at least one concavity 20 which articulates with a femoral component. Bottom surface 22 of tibial insert 12 includes dovetail elements 24 (Fig. 6). Dovetail elements 24 mate with corresponding dovetail elements 44 on tibial plateau 14. Bore 26 extends through tibial bearing insert 12 and may be aligned with corresponding cavity 43 in tibial plateau 14. Securing member 16 may be inserted through bore 26 in tibial bearing insert 12 and cavity 43 of tibial plateau 14 to lock tibial bearing insert 12 and tibial plateau 14 together and prevent relative translational movement therebetween.

Krebs '089 discloses selectively shielding Ultrahigh Molecular Weight Polyethylene ("UHMWPE") during irradiation to selectively crosslink certain areas of the UHMWPE. For example, it may be desirable to restrict crosslinking to specific surfaces or areas of an orthopaedic device.

Applicant respectfully submits that independent Claim 1 is not obvious over O'Neil '461 in view of Krebs '089, as neither O'Neil '461 nor Krebs '089 either alone or in combination disclose or suggest each and every limitation called for in amended independent Claim 1. Specifically, independent Claim 1 calls for a tibial implant including, *inter alia*, a first articular bearing component, a second articular bearing component, an articular bearing component, an intercondylar component, and at least one pin, the first articular bearing component, the second articular bearing component, and the articular component being *joined together by the pin extending into each of the components*.

In forming the rejection, the Examiner identifies tibial plateau 14 as the first bearing component, tibial bearing insert 12 as the second bearing component, elevated spine member

36 of tibial bearing component 12 as the intercondylar component, and securing member 16 as the pin, as called for in independent Claim 1. However, independent Claim 1 calls for a first articular bearing component, a second articular bearing component, and an intercondylar component being *joined together by the pin extending into each of the components*.

In contrast to independent Claim 1, O'Neil '461 discloses securing mechanism 16 which only joins together two components, tibial bearing insert 12 and tibial plateau 14. Elevated spine 36 is an integral part of tibial bearing insert 12 and is joined to neither tibial bearing insert 12 nor tibial plateau 14 by securing mechanism 16. Advantageously, in contrast to the device disclosed in O'Neil '461, by joining the components together by a pin extending into each of the components, the individual components of the tibial knee implant may be combined to create a prosthesis that best fits the needs of an individual patient. For example, specific components of the tibial implant may be subjected to different stresses in different patients. Thus, by selecting components that are most likely to withstand those stresses, i.e., have the most desirable material properties, such as wear, toughness, and loading characteristics, a implant can be created to provide the greatest benefit for the individual patient. *See* ¶[0018] of the present application.

The Examiner's additional citation of Krebs '089 fails to overcome a deficiency of O'Neil '461, as neither Krebs '089 nor O'Neil '461 either alone or in combination disclose or suggest a first articular bearing component, a second articular bearing component, an intercondylar component, and at least one pin, the first articular bearing component, the second articular bearing component, and the intercondylar component being joined together by the pin extending into each of the components.

For the foregoing reasons, Applicant respectfully submits that independent Claim 1, as well as Claims 2-6, 9, and 12, are not obvious over O'Neil '461 in view of Krebs '089.

Claims 1-2, 7-9, and 12 are rejected under 35 U.S.C. § 103(a) as being obvious over O'Neil '461 in view of U.S. Patent No. 5,123,928 to Moser ("Moser '928").

Referring to Fig. 2 of Moser '928, Moser '928 discloses tibial component 2 having a plastic overlay 9 positioned thereon.

Applicant respectfully submits that independent Claim 1 is not obvious over O'Neil '461 in view of Moser '928. Specifically, amended independent Claim 1 calls for a tibial knee implant including, *inter alia*, a first articular bearing component, a second articular bearing component, an intercondylar component, and at least one pin, a first articular bearing component, the second articular bearing component, and the intercondylar component *being joined together by the pin extending into each of the components*.

In forming the rejection, the Examiner relies on O'Neil '461 as disclosing or suggesting each of the limitations of independent Claim 1. However, for the reasons set forth above, O'Neil '461 fails to disclose or suggest each and every limitation of amended independent Claim 1. The Examiner's additional citation of Moser '928 fails to overcome this deficiency, as neither Moser '928 nor O'Neil '461 either alone or in combination disclose or suggests a tibial knee implant including a first articular bearing component, a second articular bearing component, an intercondylar component, and at least one pin, the first articular bearing component, the second articular bearing component, and the intercondylar component being joined together by the pin extending into each of the components.

For the foregoing reasons, Applicant respectfully submits that independent Claim 1, as well as Claims 2, 7-9, and 12, which depend therefrom, are not obvious over O'Neil '461 in view of Moser '928.

In the event Applicant has overlooked the need for an additional extension of time, payment of fee, or additional payment of fee, Applicant hereby petitions therefor and authorizes that any charges be made to Deposit Account No. 02-0385, Baker & Daniels.

Should the Examiner have any further questions regarding any of the foregoing, he is respectfully invited to telephone the undersigned at 260-424-8000.

Respectfully submitted,

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## **CERTIFICATION OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on: June 1, 2007

MATTHEW B. SKAGGS, REG. NO. 55,814

Name of Registered Representative

Signature

June 1, 2007

Date